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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,582	12/20/2001	Patrick Soon-Shiong	VIVOR1420-1 (073799-1107)	6249
30542	7590	01/07/2004	EXAMINER	
FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/029,582

Applicant(s)

SOON-SHIONG ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 39-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 39-52 and 54-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 10/30/03 wherein claim 53 and the specification were amended.

**Note:** Claims 1-6 and 39-64 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments filed 10/30/03 to the rejection of claim 53 made by the Examiner under 35 USC 103 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 4/21/03 and those set forth below.

### **103 Rejection**

The rejection of claim 53 under 35 USC 103(a) as being unpatentable over Dionne et al (US Patent No. 5,874,099) is MAINTAINED for reasons of record in the office action mailed 4/21/03 and those set forth below.

Applicant asserts that the instant invention is distinguished over the cited prior art because Dionne et al does not teach or suggest a microcapsule which contains at least one cell aggregate inside a core that is not ionically linked and an outer layer that is covalently crosslinked, polyionically crosslinked or both covalent and polyionically crosslinked, but not ionically crosslinked.

Ionic bonding as defined by any standard chemical dictionary refers to the formation of ions by transfer of one or more electrons from one atom to another. In other words, the electrostatic attraction between oppositely charged ions. Column 15, lines 16-26 of Dionne et al disclose that the jacket (outer layer) may be crosslinked and

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that the formation of the vehicle does not require polymers of opposite charge to the jacket be present. Thus, a skilled practitioner in the art would recognize that based on the definition of ionic bonding that since polymers opposite charge to the jacket are not required, the jacket may be non-ionically crosslinked. Also, it should be noted that in column 15, lines 27-38, it is disclosed that the jacket may be made of a thermoplastic material or of a material such as alginated and crosslinked with a multivalent ion such as calcium.

The amending of the claim to state that the core contains at least one cell aggregate does not distinguish the instant invention over the cited prior art. Specifically, column 5, lines 56-59, disclose that the vehicle comprises a core that contains a biologically active moiety. Columns 5-6, bridging paragraph, disclose that the biologically active moiety is a tissue, cell, or other substance which is capable of exerting a biologically useful effect upon the body. Also, it should be noted that in column 7, lines 1-26, it is disclosed that the core may contain cells or tissues that tend to form aggregates. Hence, the skilled practitioner would recognize that a core containing cell aggregates is within the scope of the invention of Dionne et al.

Dionne et al disclose that the jacket may be made from hydrogels, water insoluble thermoplastic polymers (column 12, lines 40-65) and other suitable materials, which include polysaccharides (e.g., cellulose), for example (column 16, lines 35-49).

**Note:** It should be noted that in column 15, lines 32-44, specifically, lines 34-37, it is disclosed that the jacket of Dionne et al may be used for microcapsules.

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### **WITHDRAWN CLAIMS**

3. Claims 1-6, 39-52, and 54-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) for reasons of record in the office action mailed 4/21/03.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized flourish at the end.

D. L. Jones  
Primary Examiner  
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December 30, 2003